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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/540,612

07/24/2006

Mathias Farnegardh

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9118

27267

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07/12/2007

WIGGIN AND DANA LLP

ATTENTION: PATENT DOCKETING

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EXAMINER

LEE, JAE W

ART UNIT

PAPER NUMBER

1656

MAIL DATE

DELIVERY MODE

07/12/2007

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

**Application No.**

10/540,612

**Applicant(s)**

FARNEGARDH ET AL.

**Examiner**

Jae W. Lee, Ph.D.

**Art Unit**

1656

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 16 October 2006.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-39 are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                       | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)   | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

Art Unit: 1656

## **DETAILED ACTION**

### ***Application status***

Claims 1-39 are pending in the instant application.

### ***Election/Restrictions***

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1-12, 29-32 and 35, drawn to a crystal comprising at least 150 amino acid residues of the LXR $\beta$  ligand binding domain, and an isolated protein consisting essentially of the amino acid sequence shown from amino acid 220 to amino acid 461 in FIG. 5a (SEQ ID NO: 1) or the sequence shown in FIG. 5b (SEQ ID NO: 2).

Group II, claim(s) 13-19 and 21-28, drawn to a drug screening assay comprising the steps of: (a) selecting a potential ligand by performing rational drug design with the three-dimensional structure determined for the crystal of claim I, wherein said selecting is performed in conjunction with computer modeling; (b) contacting (i.e. docking) the potential ligand with the ligand binding domain of LXR $\beta$ ; and (c) detecting the binding of the potential ligand for the ligand binding domain

Group III, claim(s) 20, 36 and 37, drawn to a machine-readable data storage medium, comprising a data storage material encoded with machine readable data which, using a machine programmed with instructions for using said data, is capable of displaying a graphical three-dimensional representation of a crystal structure according to claim 1 or a homologue of said crystal structure.

Group IV, claim(s) 33 and 34, drawn to a vector, such as a plasmid, containing a nucleic acid molecule encoding a protein consisting of the amino acid sequence shown from

Art Unit: 1656

220 to 461 in FIG. 5a (SEQ ID NO: 1) or the sequence shown in FIG. 5b (SEQ ID NO: 2); and a host cell containing a vector according to claim 33.

Group V, claim(s) 38 and 39, drawn to a method for determining the three-dimensional structure of a complex between LXR $\beta$  and a ligand therefore, which comprises: (a) obtaining x-ray diffraction data for crystals of the complex as defined in claim 1; and (b) utilizing a set of atomic coordinates as defined in claim 29 or a portion thereof; and coordinates having a root mean square deviation therefrom with respect to conserved protein backbone atoms of not more than 1.5 angstrom to define the three-dimensional structure of the complex.

In addition to the above election, please elect a single SEQ ID NO. This application contains claims directed to the following patentably distinct species: SEQ ID NO: 2, SEQ ID NO: 4 or SEQ ID NO: 6.

In addition to the above elections, please elect a single cysteine position from the list in claim 11 for corresponding SEQ ID NO that Applicants have elected above.

Therefore, please elect a single amino acid position from

(A) 66, 69 or 70 if the Applicants have elected SEQ ID NO: 2 or

(B) 56, 59 or 60 if the Applicants have elected SEQ ID NO: 4 or

(C) 37, 40 or 41 if the Applicants have elected SEQ ID NO: 6.

The species are independent or distinct, and do not share unity of invention, because these SEQ ID NOs and distinct mutations of cysteine residues at specific positions represent structurally different amino acid sequences. Therefore, where structural identity is required, such as for hybridization or expression, the different

sequences have different effects.

These claims will be examined to the extent they read upon the elected species.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 1-39 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which depend from or otherwise require all the limitations of an allowable generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species.  
MPEP § 809.02(a).

The inventions listed as Groups I-V do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression

Art Unit: 1656

"special technical features" shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. The reference of Rodan et al. (US Patent No. 5,939,322) teaches a human steroid hormone receptor comprising an amino acid sequence of SEQ ID NO: 2 (see below columns 7 and 8), which corresponds to the limitation of claim 30, in the recitation of "[a] crystallisable composition comprising at least 150 amino acid residues of the LXR $\beta$  ligand-binding domain," and thus, the shared technical feature of the groups is not a "special technical feature", unity of invention between the groups does not exist. Please refer to the sequence alignment result between SEQ ID NO: 2 of US Patent No. 5,939,322, and the full-length sequence of LXR $\beta$  as set forth in SEQ ID NO: 1 of the instant application, which shows that amino acid residues from 52-461 of these sequences are identical (please see attached).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(l).

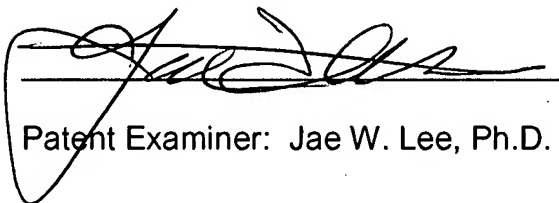
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jae W. Lee whose telephone number is 571-272-9949. The examiner can normally be reached on 8:00-4:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kathleen Kerr Bragdon can be reached on 571-272-0931. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

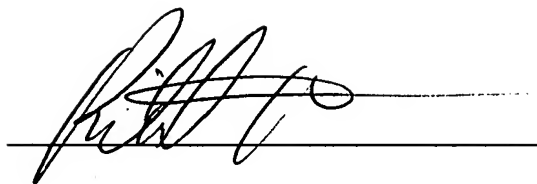
Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Application/Control Number: 10/540,612  
Art Unit: 1656

Page 7



Patent Examiner: Jae W. Lee, Ph.D.



**RICHARD HUTSON, PH.D.**  
**PRIMARY EXAMINER**